Case Number:	CM13-0029011		
Date Assigned:	11/27/2013	**Date of Injury:**	03/09/2012
Decision Date:	05/13/2014	**UR Denial Date:**	09/17/2013
Priority:	Standard	**Application Received:**	09/24/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a Physician Reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The Physician Reviewer is Board Certified in Physical Medicine & Rehabilitation, has a subspecialty in Pain Medicine, and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The Physician Reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 51-year-old female with a date of injury of March 9, 2012. The injured worker's diagnoses consist of chronic low back pain, lumbar radiculopathy, and lumbar foraminal stenosis. Lumbar MRI on date of service April 2, 2012 demonstrated degenerative disc disease at multiple levels and right posterior lateral disc protrusion at L4 5. There was also severe neuroforaminal narrowing noted at L5 S1. The patient has been treated with conservative care including pain medications, activity modification, and physical therapy. The patient also had previous transforaminal epidural steroid injection with one day of pain relief on October 12, 2012. . The disputed requests include a transforaminal epidural steroid injection, surgical consultation, omeprazole, Vicodin 7.5/500 mg, Soma, and Lidoderm patches.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

TRANSFORAMINAL EPIDURAL STEROID INJECTION ON THE RIGHT SIDE AT L5: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines EPIDURAL STEROID INJECTION.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines EPIDURAL SECTION Page(s): 47.

Decision rationale: The California Medical Treatment and Utilization Schedule specifies on page 47 of the Chronic Pain Medical Treatment Guidelines the following regarding Epidural steroid injections (ESIs) ESIs are recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy). Most current guidelines recommend no more than 2 ESI injections. This is in contradiction to previous generally cited recommendations for a "series of three" ESIs. These early recommendations were primarily based on anecdotal evidence. Research has now shown that, on average, less than two injections are required for a successful ESI outcome. Current recommendations suggest a second epidural injection if partial success is produced with the first injection, and a third ESI is rarely recommended. Epidural steroid injection can offer short term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program. There is little information on improved function. The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. Note: The purpose of ESI is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit. 1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. 2) The patient must be initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants). 3) Injections should be performed using fluoroscopy (live x-ray) for guidance. 4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections. 5) No more than two nerve root levels should be injected using transforaminal blocks. 6) No more than one interlaminar level should be injected at one session. 7) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. 8) Current research does not support a "series-of-three" injections in either the diagnostic or therapeutic phase. It is recommended that there be no more than 2 ESIs. Although there is documentation that this injured worker had a previous transforaminal epidural steroid injection that only resulted in short term relief, it is reasonable to attempt another transforaminal epidural steroid injection. There may be some instances where an epidural injection is not placed in the correct location despite fluoroscopy guidance. The guidelines do allow up to 2 consecutive epidural steroid injections. Clearly the goal of the epidural steroid injection is to avoid decompressive surgery, which the injured worker has already been recommended if all other conservative efforts fail. Given the documentation on lumbar MRI and the physical examination, the request for one more transforaminal epidural steroid injection is recommended for certification.

SURGICAL CONSULT: Overturned

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 305.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation INEDPENDENT MEDICAL EXAMINATIONS AND

CONSULTATIONS CHAPTER (ACOEM PRACTICE GUIDELINES, 2ND EDITION (2004), CHAPTER 7) PAGE 127.

Decision rationale: The California Medical Treatment and Utilization Schedule does not have specific guidelines with regard to consulting specialists. American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Second Edition indicate the following on page 127: "The occupational health practitioner may refer to other specialists if a diagnosis is uncertain or extremely complex, when psychosocial factors are present, or when the plan or course of care may benefit from additional expertise. An independent medical assessment also may be useful in avoiding potential conflict(s) of interest when analyzing causation or when prognosis, degree of impairment, or work capacity requires clarification. When a physician is responsible for performing an isolated assessment of an examinee's health or disability for an employer, business, or insurer, a limited examinee-physician relationship should be considered to exist." In the case of this injured worker, multiple conservative efforts at addressing low back pain and lumbar radiculopathy have not been successful. The injured worker has tried physical therapy and is on multiple pain medications. Given the lumbar MRI findings, it is reasonable to seek surgical consultation given this clinical picture.

OMEPRAZOLE 10MG #30: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS GI SYMPTOMS & CARDIOVASCULAR RISK.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines PPI SECTION Page(s): 68-69.

Decision rationale: The Chronic Pain Medical Treatment Guidelines on page 68-69 states the following regarding the usage of proton pump inhibitors (PPI): "Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. Recommendations Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 Âµg four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture. Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxen plus low-dose aspirin plus a PPI. In the case of this injured worker, there is documentation that the injured worker suffers from gastrointestinal upset due to taking ibuprofen. This is documented in a progress note on August 8, 2013. Given this, it is appropriate to have gastrointestinal prophylaxis with a proton pump inhibitor. This request is recommended for certification.

VICODIN 7.5/500MG #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS SPECIFIC DRUG LIST.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 76-80. Decision based on Non-MTUS Citation FDA GUIDELINES REGARDING ACETAMINOPHEN AND OPIOID COMBINATION MEDICATIONS.

Decision rationale: The Chronic Pain Medical Treatment Guidelines on pages 76-80 indicate the following criteria for the ongoing use of opioids, including: "Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." In the case of this request, the FDA has requested opioid drug manufacturers to limit the strength of acetaminophen to no more than 325 mg per dosage units due to possible liver toxicity and side effects. Therefore, this request is recommended for non-certification. Non-certification does not equate with abrupt cessation, and the requesting healthcare provider should either taper this dosage or consider requesting a formulation that is in accordance with FDA guidelines.

SOMA 350MG #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines SOMA.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines MUSCLE RELAXANT Page(s): 65.

Decision rationale: The Chronic Pain Medical Treatment Guidelines on page 65 states the following regarding carisoprodol (Soma): "Carisoprodol (SomaÂ®, Soprodal 350â¿¢, VanadomÂ®, generic available): Neither of these formulations is recommended for longer than a 2 to 3 week period. Carisoprodol is metabolized to meprobamate, an anixolytic that is a schedule IV controlled substance. Carisoprodol is classified as a schedule IV drug in several states but not on a federal level. It is suggested that its main effect is due to generalized sedation as well as treatment of anxiety. This drug was approved for marketing before the FDA required clinical studies to prove safety and efficacy. Withdrawal symptoms may occur with abrupt discontinuation. In the case of this injured worker, there is no clear documentation of the clinical efficacy of soma. This medication has been prescribed since at least February 2013. The

guidelines recommend short-term usage of this medication given the risk of physical dependence. This request is recommended for non-certification.

LIDODERM PATCH #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines LIDODERM.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

Decision rationale: The Chronic Pain Medical Treatment Guidelines on pages 112-113 specify the following regarding topical Lidocaine: "Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (LidodermÂ®) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo." In the case of this injured worker, there is no documentation of localized peripheral neuropathic pain that is amenable to topical treatment. Although there is documentation of lumbar radiculopathy, this is not localized peripheral pain (such as diabetic neuropathy or shingles). The guidelines do not recommend this for chronic musculoskeletal low back pain. This request is recommended for non-certification.